January 12, 2006

VIA FACSIMILE/CONFIRMATION BY OVERNIGHT DELIVERY

Timothy J. Couzins
Compliance Officer
Florida District Office
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

Re: Response to FDA Warning Letter FLA-06-08

Dear Mr. Couzins:

We are writing to respond to the warning letter issued by the Florida District Office on December 2, 2005, and received on December 9, 2005, regarding the Anodyne Therapy System infrared lamp (Class II) device, which is manufactured and distributed by Anodyne Therapy, LLC ("Anodyne"). We appreciate your agreement to the extension of our due-date response to January 13, 2006.

The letter stated that you believe the product labeling and internet website in use at the time of FDA's inspection promoted the Anodyne Therapy System for intended uses that exceeded Anodyne's existing 510(k) marketing clearance. Although similar claims are being made by at least two other companies, one without a 510(k) clearance, we will not identify specific conditions that may benefit from the cleared claim. Anodyne has revised its website and its product labeling to identify only the indications of increasing circulation and reducing pain that were cleared by FDA (K931261). We have also implemented a new standard operating procedure, effective December 2005, regarding the review and dissemination of all promotional materials. Finally, Anodyne is preparing a 510(k) premarketing submission for new, additional indications, and we intend to transmit the submission to FDA shortly.

The letter of December 2nd also repeated a number of Quality System Regulation-related observations from the FDA-483, dated July 1, 2005. As you know, Anodyne provided the Florida District Office with a detailed response to the FDA-483 on August 12, 2005, which outlined specific and detailed corrective actions that Anodyne would undertake to address the inspectional observations contained in the FDA-483. We

understand from a conversation with our regulatory counsel, Paul Ferrari of Hyman, Phelps & McNamara, P.C., that the identified corrective actions are adequate to address the observations once those actions are completed. Anodyne provided the Florida District Office with status report of our corrective actions on January 12, 2006. As indicated in the status report, the last corrective action will be completed by January 31, 2006.

Finally, it is our understanding that the FDA has initiated a policy whereby responses to warning letters may be posted on the FDA Internet website at the warning letter recipient's request. We therefore request that this response letter be posted on the FDA website. We have enclosed with the original, hard copy of our response, transmitted via overnight delivery, a computer diskette containing an electronic version of this response in Word format for your use.

Sincerely,

Craig H. Turtzo
President

cc: Emma R. Singleton, Director, FDA/Florida DO
(facsimile copy only)